

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

O R D E R

This matter is before the Court on the motion for summary judgment filed by the Inspector General (Doc. No. 12). For the reasons set forth below, the Inspector General's motion for summary judgment is well-taken and is **GRANTED**.

The material facts in this case are not disputed. On November 30, 2004, Plaintiff Kevin J. Bowers, a registered pharmacist in the State of Ohio, entered guilty pleas to charges of tampering with drugs, in violation of Ohio Rev. Code § 2925.24(A), and theft of drugs, in violation of Ohio Rev. Code § 2913.02(A)(2). The tampering offense is a third degree felony and the theft offense is a fourth degree felony. The charges came about because Bowers had been stealing Tussionex (hydrocodone), a controlled substance, during his employment as a pharmacist with Walgreen's Pharmacy. The state court sentenced Bowers to two years of community control on each count.

On September 19, 2005, the Ohio State Board of Pharmacy indefinitely suspended Bowers' license to practice pharmacy. Additionally, on October 26, 2005, the Board transmitted notice of Bowers' suspension to the Inspector General of the Department of Health and Human Services.

On November 2, 2006, the Inspector General notified Bowers of his intent, pursuant to 42 U.S.C. § 1320a-7(a), to exclude Bowers from participating in Medicare, Medicaid, and all federal health care programs as a result of his convictions. Section § 1320a-7(a)(1) mandates exclusion from these programs when an individual or entity "as been convicted of a criminal offense related to the delivery of an item or service under subchapter XVIII of this chapter or under any State health care program." The notice provided Bowers with a 30 day period in which to submit supporting documentation to the Office of Inspector General ("OIG") before a final decision concerning Bowers' exclusion was rendered. Bowers submitted in timely fashion a letter to the OIG explaining why his exclusion would not be justified. On April 30, 2007, Bowers received a notice of his exclusion from the OIG for the minimum statutory period of five years.

Bowers requested and received a hearing before an administrative law judge ("ALJ") pursuant to 42 C.F.R. § 1001.2007. The matter was submitted to the ALJ on briefs.

Bowers argued before the ALJ that his exclusion pursuant to § 1320a-7(a)(1) was not warranted because his theft of Tussionex was for personal use and, therefore, was not related to the delivery of a healthcare item or service. Bowers also argued that OIG was barred from excluding him under the doctrine of laches because two years elapsed between the entry of his guilty pleas and the OIG's action excluding him from these federal health care programs.

On September 27, 2007, the ALJ issued a decision sustaining Bowers' five year exclusion from participating in Medicare, Medicaid, and all other federal healthcare plans. Complaint Ex. A. In rejecting Bowers' first argument, the ALJ stated that Bowers would not have had access to the Tussionex but for his job as a pharmacist. Moreover, the ALJ reasoned that the Tussionex was in the stream of commerce from the manufacturer to its ultimate destination to patients with legitimate prescriptions for the drug. The pharmacy was a transit point for the drug, the ALJ stated, and but for Bowers' theft, the drug would have eventually been lawfully delivered to the patients. Therefore, the ALJ concluded that Bowers' crimes were related to the delivery of a health care item. The ALJ did not address Bowers' laches defense on the grounds that he was limited by statute to deciding only whether the Inspector General was required to exclude Bowers.

On January 8, 2008, the Departmental Appeals Board ("DAB") issued a final decision affirming the ALJ's ruling. Complaint, Ex. B. The DAB's rationale for finding that Bowers' offenses were related to the delivery of a health care item were the same as the ALJ's. Likewise, the DAB concluded that it lacked statutory authority to consider Bowers' laches defense.

On March 10, 2008, Bowers filed a complaint for review of the Inspector General's decision excluding him from participation in federal health care programs pursuant to 42 U.S.C. § 1320a-7(f)(1) and 42 U.S.C. § 405(g). In his complaint, Bowers asserts that the decision excluding him was not supported by substantial evidence and that the OIG's action against him is barred by the doctrine of laches. Bowers also advanced a number of constitutional due process grounds for reversal of the OIG's decision which he has apparently now abandoned. As indicated, the parties agree that the facts are not in dispute. Essentially, then, this case presents two questions of law: 1) whether the OIG's interpretation of § 1320a-7(a) as applied to Bowers' case is entitled to deference; and 2) whether the OIG's action is barred by laches.

A. Standard of Review

Pursuant to 42 U.S.C. § 405(g), the Court is to determine only whether the record as a whole contains substantial evidence to support the ALJ's decision. "Substantial evidence

means more than a mere scintilla of evidence, such as evidence as a reasonable mind might accept as adequate to support a conclusion." LeMaster v. Secretary of Health & Human Serv., 802 F.2d 839, 840 (6th Cir. 1986) (internal citation omitted). The evidence must do more than create a suspicion of the existence of the fact to be established. Id. Rather, the evidence must be enough to withstand, if it were a trial to a jury, a motion for a directed verdict when the conclusion sought to be drawn from it is one of fact for the jury. Id. If the ALJ's decision is supported by substantial evidence, the Court must affirm that decision even if it would have arrived at a different conclusion based on the same evidence. Elkins v. Secretary of Health & Human Serv., 658 F.2d 437, 439 (6th Cir. 1981).

In this case, however, the ALJ's factual findings are not in dispute. Rather, his construction of § 1320a-7(a)(1) is contested. In Kentucky Waters Alliance v. Johnson, 540 F.3d 466 (6th Cir. 2008), the Court set forth the standard of review of an agency's interpretation of a federal statute:

In reviewing a federal agency's interpretation of a statute that it administers, a reviewing court must first ask whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. However, if Congress has not directly addressed the precise question at issue and the statute is silent or ambiguous with respect to the specific issue, then the question for the court is whether the agency's answer is based on a permissible construction of the statute.

If the agency's construction is a permissible one, even if it is not the reading the court would have reached if the question initially had arisen in a judicial proceeding, then the court must defer to the agency's interpretation. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.

Id. at 474-75 (summarizing Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984)) (internal citations, brackets, and quotation marks omitted). In this case, the OIG's interpretation of § 1320a-7(a)(1) is entitled to so-called Chevron deference because it was rendered in the context of an adjudication. See Mid-America Care Foundation v. N.L.R.B., 148 F.3d 638, 642 (6th Cir. 1998); see also Commodity Futures Trading Comm'n v. Erskine, 512 F.3d 309, 314 (6th Cir. 2008) (noting that commission's interpretation of "futures contract" would have been entitled to Chevron deference had it been defined in an adjudication). If the agency's construction is permissible, it controls unless "arbitrary, capricious, or manifestly contrary to the statute." Sad v. I.N.S., 246 F.3d 811, 815 (6th Cir. 2001) (quoting Chevron, 467 U.S. at 844).

B. Analysis

1. Section 1320a-7(a)(1)

The ALJ's determination that Bower's theft of Tussionex for personal use was related to the delivery of a health care item, and therefore, mandates his exclusion from participation in

federal health care programs, is a permissible construction of 42 U.S.C. § 1320a-7(a)(1).

The Court first notes Congress has not defined when a criminal offense is "related to the delivery of a [health care] item." Therefore, in this regard, the statute is ambiguous as to the issue presented here. See Harris v. Olszewski, 442 F.3d 456, 466 (6th Cir. 2006) ("In establishing an exception to Medicaid's freedom-of-choice provision for 'medical devices,' Congress did not define the phrase and thus did not use the most natural means for eliminating ambiguity about it."). Accordingly, the question becomes whether the OIG's interpretation of § 1320a-7(a)(1) is permissible.

It clearly is. One of the reasons for the exclusion provisions is that persons who commit offenses like Bowers did in this case "deprive patients of needed services or supplies, and they divert taxpayer funds from their intended purposes."

Manocchio v. Kusserow, 961 F.2d 1539, 1542 (11th Cir. 1992) (quoting 133 Cong.Rec. 14,177 (statement of Rep. Waxman, Chairman, House Subcommittee on Health and the Environment)). Moreover, the Department of Health and Human Services has stated that the exclusion provisions "serve to recognize the seriousness of such felony convictions and ensure that beneficiaries of the Medicare and State health care programs are well protected from dealing with such individuals and entities." See Health Care

Programs: Fraud and Abuse; Revised OIG Exclusion Authorities Resulting From Public Law 104-191, 62 Fed. Reg. 47182-1, at 47183 (Sept. 8, 1997). Thus, the OIG's broad interpretation of "related to" is consistent with the goal of enhancing protection for health care beneficiaries. Additionally, the OIG has consistently interpreted § 1320a-7(a)(1) to apply in situations where the individual stole (or attempted to steal) drugs for personal use. E.g., Andrew D. Goddard, DAB No. 2032 (2006); Kenneth M. Behr, DAB No. 1997 (2005); Erik D. DeSimone, DAB No. 1932 (2004); Howard Schwartz, DAB No. CR1752 (2008); e.g., Skidmore v. Swift & Co., 323 U.S. 134, 140 (1940).¹ Consequently, it is certainly a rational construction of § 1320a-7(a)(1) to conclude that offenses that divert drugs from the legitimate end-users, such as Bowers committed in this case, are related to the delivery of a health care item.

Accordingly, the Court concludes that the OIG's interpretation of § 1320a-7(a)(1) to mandate exclusion from federal health care programs where a pharmacist diverts drugs for his personal use is entitled to complete deference.

B. Laches

¹ The Court recognizes that so-called "Skidmore deference" gives agency interpretations less deference than Chevron deference. Nevertheless, the Court believes that consistency of opinion, one of the factors for consideration under Skidmore, is still a relevant consideration in this case.

Bowers also argues that the OIG's action against him should be barred by the doctrine of laches because of the delay between the entry of his guilty pleas and his exclusion from the programs by the OIG. Laches is an affirmative defense which requires the proof of two elements: 1) lack of diligence by the party against whom the defense is asserted, and 2) prejudice to the party asserting the defense. See Cleveland Newspaper Guild, Local 1 v. Plain Dealer Publ'g Co., 839 F.2d 1147, 1153 (6th Cir. 1988). Laches, however, is not available as a defense against the government. United States v. Weintraub, 613 F.2d 612, 618 (6th Cir. 1979) ("It is well established that the Government generally is exempt from the consequences of its laches."); see also United States v. Kirkpatrick, 22 U.S. (9 Wheat.) 720, 735 (1824) (Story, J.) ("The government can transact its business only through its agents; and its fiscal operations are so various, and its agencies so numerous and scattered, that the utmost vigilance would not save the public from the most serious losses, if the doctrine of laches can be applied to its transactions"); United States v. Peoples Household Furnishings, Inc., 75 F.3d 252, 254 (6th Cir. 1996) ("The ancient rule quod nullum tempus occurrit regi - 'that the sovereign is exempt from the consequences of its laches, and from the operation of statutes of limitations' - has enjoyed continuing vitality for centuries.").

Conclusion

In conclusion, the record demonstrates that the OIG's interpretation of § 1320a-7(a)(1) to apply in this case and to mandate Bowers' exclusion from participation in federal health care programs due to his criminal convictions for theft of drugs for personal use is a permissible construction of the statute. Additionally, the Court finds that the defense of laches cannot be asserted against the agency as a matter of law.

Accordingly, the Inspector General's motion for summary judgment is well-taken and is **GRANTED**. The complaint is **DISMISSED WITH PREJUDICE**.

IT IS SO ORDERED

Date December 19, 2008

s/Sandra S. Beckwith
Sandra S. Beckwith, Chief Judge
United States District Court